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K013304/

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BD

Indispensable to human health

Premarket Notification [510(k)] Summary of Safety and Effectiveness for BD Introsyte™ Precision Introducer and BD Introsyte™ Autoguard™ Shielded Introducer

Submitter:	Becton Dickinson Infusion Therapy Systems Inc.
Address:	9450 South State Street Sandy, UT 84070
Contact Person:	Leslie Wood, Manager, Regulatory Affairs
Telephone Number:	(801) 565-2504
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Date Summary Prepared:	September 27, 2001
Trade Names:	BD Introsyte™ Precision Introducer BD Introsyte™ Autoguard™ Shielded Introducer
Common Name:	Introducer Catheter
Classification Name:	Introducer Catheter
Predicate Devices:	Same as trade names listed above.

Product Descriptions:

The products identified in this 510(k) notification are splittable, polyethylene introducer catheters. The BD Introsyte™ Autoguard™ Shielded Introducer includes a needle-shielding feature that the BD Introsyte™ Precision Introducer does not include. Autoguard products incorporate spring-activated needle-shielding technology. The Autoguard component incorporates a cylindrical needle-shielding barrel, a spring, a needle hub with flash chamber and hydrophobic flow control plug, and a needle. The user-activated Autoguard™ product has a button, which the user pushes to initiate the needle's retraction into the needle-shielding barrel.

The Introsyte introducers are available in sizes ranging from 14 to 24 gauge.

Intended Use:

An introducer catheter is used to facilitate the placement of devices such as guide wires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Technological Characteristics Comparison:

The catheter design and technological characteristics have not changed. The lubrication systems used have been modified to make the manufacturing process 'ozone friendly.'

Nonclinical Tests Support Substantial Equivalence:

Side-by-side testing of modified and unmodified devices was conducted to compare product attributes.

Conclusions from Nonclinical Tests:

Data have been provided to demonstrate that product performance and biocompatibility are substantially equivalent between the modified and unmodified devices.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 2 2002

Ms. Leslie Wood
Manager, Regulatory Affairs
Becton Dickinson Infusion Theraphy Systems Inc.
9450 South State Street
Sandy, UT 84070

Re: K013304
BD Introsyte™ Precision Introducer, BD Introsyte™ Autoguard™ Shielded Introducer
Regulation Number: 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: Class II
Product Code: DBY
Dated: October 3, 2001
Received: October 4, 2001

Dear Ms. Wood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Becton Dickinson Infusion Therapy Systems Inc.
Sandy, UT 84070

INDICATIONS FOR USE

Device Name: BD Introsyte™ Precision Introducer
BD Introsyte™ Autoguard™ Shielded Introducer

To facilitate the placement of devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The Counter Use: _____
(per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013304